Court of Justice of the European Union
PRESS RELEASE No 06/18
Luxembourg, 23 January 2018

Press and Information

Judgment in Case C-179/16
F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato

The agreement between the pharmaceutical groups Roche and Novartis designed to reduce the use of Avastin in ophthalmology and to increase the use of Lucentis might constitute a restriction of competition 'by object'

Avastin and Lucentis are medicinal products developed by Genentech, a company which belongs to the Roche group. Genentech entrusted the commercial exploitation of Lucentis to the Novartis group by way of a licensing agreement. Roche markets Avastin.

Those biotechnological medicinal products were authorised by the Commission and the European Medicines Agency (the EMA). Lucentis is authorised for the treatment of eye diseases. Avastin, while authorised only for the treatment of tumorous diseases, is also frequently used to treat eye diseases because its price is lower than Lucentis.

In 2014, the Autorità Garante della Concorrenza e del Mercato (the Italian competition authority, Italy; the AGCM) imposed two fines, each amounting to over €90 million, on both Roche and Novartis, on the ground that those undertakings had put in place an arrangement designed to achieve an artificial differentiation between Avastin and Lucentis. According to the AGCM, Avastin and Lucentis are equivalent in all respects for the treatment of eye diseases. Furthermore, the arrangement was intended to disseminate information giving rise to concerns regarding the safety of Avastin used in ophthalmology with a view to causing a shift in demand toward Lucentis. The AGCM claims that this shift resulted in a cost increase for the Italian health service assessed at approximately €45 million in 2012 alone.

After the Tribunale amministrativo regionale per il Lazio (Regional Administrative Court, Lazio, Italy) dismissed the actions that they had brought against those fines, Roche and Novartis lodged an appeal before the Consiglio di Stato (Council of State, Italy), which referred the matter to the Court of Justice for a preliminary ruling on the interpretation of EU competition law.

In today's judgment, the Court examines first of all whether a national competition authority such as the AGCM may consider that Avastin, although not authorised for the treatment of eye diseases, forms part of the same market as Lucentis, which is specifically authorised for those diseases and, if so, whether the competition authority must take account of the possible unlawfulness of that use of Avastin under the EU rules governing pharmaceutical matters.

The Court recalls that, in principle, medicinal products that may be used for the same therapeutic indications belong to the same market. However, the fact that pharmaceutical products are manufactured or sold unlawfully prevents them from being regarded as substitutable with products manufactured and sold lawfully. Nevertheless, the EU rules governing pharmaceutical matters prohibit neither the prescription of a medicinal product outside the conditions laid down in its marketing authorisation (MA) nor its repackaging for such off-label use, provided that they comply with certain conditions. It is not for the AGCM but for the national courts or the competent authorities to verify that those conditions are satisfied. The Court then notes that, for the treatment of eye diseases, there is a specific relationship of substitutability between Lucentis and Avastin when used off label.

The Court concludes that, if the competent authorities and courts have not examined whether the conditions for the repackaging and the off-label prescription of Avastin are unlawful, the AGCM may consider that the two products are in the same market and can therefore be regarded as competing medicinal products. In so far as the competent authorities and courts have examined whether those conditions are unlawful, the AGCM must take account of the outcome of that examination.

The Court precludes that the arrangement between the Roche group and the Novartis group referred to by the AGCM may be justified as ancillary to their licensing agreement. In that regard, the Court observes that the arrangement was not designed to restrict the commercial autonomy of the parties to the licensing agreement regarding Lucentis but rather the conduct of third parties – in particular healthcare professionals – with a view to reducing the prescription of Avastin in ophthalmology for the benefit of Lucentis. In those circumstances, the arrangement cannot be considered to be ancillary and objectively necessary for the implementation of the licensing agreement.

The Court notes that an arrangement between two undertakings marketing two competing medicinal products, which consists in the dissemination, in a context of scientific uncertainty, to the EMA, healthcare professionals and the general public of misleading information relating to adverse reactions resulting from the off-label use of one of those products with a view to reducing the competitive pressure it exerts on the other product, constitutes a restriction of competition 'by object'. The Court explains that the information must be considered to be misleading (which is a matter for the national courts to determine) if its purpose is, first, to confuse the EMA and the Commission and, secondly, to emphasise, in a context of scientific uncertainty, the public perception of the risks associated with the off-label use of Avastin.

Lastly, the Court recalls that an arrangement cannot be exempt under Article 101(3) TFEU if it includes restrictions that are not indispensable. The dissemination of misleading information in respect of a medicinal product cannot be regarded as 'indispensable'. An arrangement intended to disseminate such misleading information therefore cannot be exempt.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Press contact: Holly Gallagher ☎ (+352) 4303 3355